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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/672,763

09/26/2003

David J. Yang

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1049

32425

7590

04/19/2006

FULBRIGHT & JAWORSKI L.L.P.
600 CONGRESS AVE.
SUITE 2400
AUSTIN, TX 78701

EXAMINER

JONES, DAMERON LEVEST

ART UNIT

PAPER NUMBER

1618

DATE MAILED: 04/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/672,763	Applicant(s) YANG ET AL.	
	Examiner D. L. Jones	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 52-82 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 52-58, 61-66, 69, and 79 is/are rejected.
- 7) ☒ Claim(s) 59,60,67,68,70-78 and 80-82 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the amendment filed 2/6/06 wherein claims 1-51 are canceled and claims 52 and 79 are amended.

Note: Claims 52-82 are pending.

RESPONSE TO APPLICANT'S AMENDMENT/ARGUMENTS

2. The Applicant's arguments filed 2/6/06 to the rejection of claims 52-58, 61-66, and 79 made by the Examiner under 35 USC 102 and/or 103 have been fully considered and deemed persuasive for the reasons set forth below. Therefore, all outstanding rejections are WITHDRAWN.

102 Rejections

The 102 rejections are WITHDRAWN because Applicant amended the claims to overcome the rejections.

103 Rejections

I. The 103 rejection over Kung et al is WITHDRAWN because Applicant amended the claims to overcome the rejection.

II. The 103 rejection over Auzeloux et al is WITHDRAWN because Applicant amended the claims to overcome the rejection.

III. The rejection of claims 52, 57, and 64 under 35 USC 103(a) as being unpatentable over Anderson et al (Nucl. Med. Biol., 1995, Vo. 22, No. 2, pages 165-173) is WITHDRAWN in view of the new grounds of rejection below.

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NEW GROUNDS OF REJECTION

103 Rejection

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 52-58, 61-66, 69, and 79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al (Nucl. Med. Biol., 1995, Vol. 22, No. 2, pages 165-173) in view of Auzeloux (J. Labelled Cpd. Radiopharm., 1999, Vol. 42, pages 567-579).

Anderson et al disclose N,N'-ethylene-di-L-cysteine (EC) complexes of Ga (III) and In(III). The chelates contain two nitrogens and two sulfurs (N₂S₂). N,N'-ethylene-di-L-cysteine is a N₂S₂ ligand that also contains two carboxylic acid moieties for complexation of Ga(III) and In(III). Also, Anderson et al discloses that because of the high thermodynamic and in vivo stability of In-EC, derivatives of EC may have applications as bifunctional chelates for ¹¹¹In labeled proteins and peptides. The ⁶⁸Ga-EC complex are possible myocardial PET imaging agents. The radiolabeled complex was injected into rat and various tissues and organs (e.g., lung, liver, and brain) were observed (see entire document, especially, abstract; page 167-168, bridging paragraph; page 171, Table 5; page 172, Table 6). However, Anderson et al fail to specifically disclose a method of imaging wherein ⁶⁸Ga is utilized even though the reference discloses that that lipophilic analogues of ⁶⁸Ga-EC have potential as

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myocardial PET imaging agents. In addition, Anderson et al fail to disclose a targeting moiety (i.e., protein or peptide) attached to EC. Furthermore, Anderson et al does not specifically state that their BAT targeting ligand is administered to humans.

Auzeloux et al disclose Tc-99m bisaminoethanethiol (BAT) derivatives that have potential as a melanoma tracer agent. The radiolabeled BAT complexes were administered to a mice and various organs such as the liver, lung, and brain were analyzed (see entire document, especially, page 567, 'Summary'; page 568; page 568, third complete paragraph; page 569, Figure 3; page 572, 'Biological Results'; page 572, Table 3; page 578, 'Biological'). While Auzeloux et al does not disclose a dicarboxylic acid containing BAT moiety, the reference is cited for its teachings that labeled BAT imaging agents may be used to evaluate tumors in locations such as the liver, lung, and brain.

While Anderson et al fail to specifically disclose a targeting moiety (i.e., peptide or protein) conjugated to EC, one would be motivated to attach a targeting moiety because the reference discloses that EC derivatives may have applications as bifunctional chelates for radiolabeled proteins and peptides because of the derivatives high thermodynamic and in vivo stability. Thus, both Anderson et al and Applicant disclose a method of imaging a site within a subject wherein one would be motivated to administer a radionuclide labeled bisaminoethanethiol (BAT) targeting ligand conjugate to a subject.

It would have been obvious to one of ordinary skill in the art to use a ^{68}Ga labeled targeting agent because Anderson et al disclose that ^{68}Ga -EC has potential as

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a possible PET imaging agent (see the last line of the abstract). In addition, Anderson et al fail to disclose their conjugate being administered to a human. However, it would be obvious to administer the radiolabeled BAT conjugate to a human because both the rat and human are mammals, thus, one of ordinary skill in the art would be motivated to administer the labeled conjugate to various mammals.

In regards to Anderson et al not specifically stating that their composition may be administered to a human, one of ordinary skill in the art would recognize the following. Both rats and humans are mammals. Thus, it would be obvious to a skilled practitioner in the art to use rats in the experimental process and then use the data obtained from the experiments for humans. Also, a skilled practitioner would recognize that rats are used in biological and medical studies because they are very close relative of humans on the tree of evolution. Thus, if one can solve a health problem using a rat, there is a good chance one can use a similar method to cure sick people. Also, if one tests a new product on a rat and it gets sick, one would recognize that the product might be too dangerous for humans as well. Modern medical studies use rats as living models of human health and disease. It is the ability of rats as a model to predict the human response accurately that makes them the animal of choice. Thus, one would be motivated to use the data from Anderson et al with humans.

Furthermore, a skilled practitioner in the art would recognize that Anderson et al and Auzeloux et al disclose structurally similar compounds, BAT conjugates may be used to image various tumors in areas such as the liver, lung, and brain.

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Since both Anderson et al and Auzeloux et al are directed to BAT conjugates, the references may be considered to be within the same field of endeavor. Hence, the reference teachings are combinable.

CLAIM OBJECTIONS

5. Claims 59, 60, 67, 68, 70-78, and 80-82 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Note: The claims are distinguished over the prior art of record because the prior art neither anticipates nor renders obvious the limitation in the dependent claims in combination with their respective intervening claims.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'D. L. Jones', is positioned above the printed name.

D. L. Jones
Primary Examiner
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April 17, 2006